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EXAMINER	
YOUNG, MICAH PAUL	
ART UNIT	PAPER NUMBER
1618	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/955,657	WOOLEY ET AL.	
	Examiner	Art Unit	
	MICAH-PAUL YOUNG	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 December 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,5-15,18-22 and 56-62* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,5-15,18-22 and 56-62* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgment of Papers Received: Remarks dated 12/08/09

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 2, 5-15, 18-22 and 56-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Fischetti et al (USPN 6,423,299 hereafter '299) in view of Farca et al, (*Potentiation of antibiotic activity by EDTA-Tromethamine against three clinically isolated Gram-Positive resistant bacteria, an* in vitro *investigation*, Veterinary Research Communications, **18**, 1994, pp 1-6) and Viegas et al (USPN 5,958,443 hereafter '443).

The '299 patent disclose a method of inhibiting the proliferation of bacterial infections in various locations including burns and oral mucosa (abstract, claims, col. 8, lin. 12-35), wherein a composition comprising a chelating agent and an active antibacterial formulation is applied to the injury (claims, examples, col. 9, lin. 62-col. 10, lin. 5). Injuries include burns to the skin (col.

12, lin. 9-14). The chelating agent includes ETDA (claims 5) and the antibacterial agents include neomycin erythromycin, minocycline, tetracycline, and others in a concentration from 0.5-10% (col. 9, lin. 19-28). The chelating agents are included in such a way as to synergistically enhance the other components in the formulation (col. 11, lin. 30-32). The formulation comprises phosphate buffers that regulate the pH of the formulation from 5.5-7.5 (col. 7, lin. 55-60). The bacterial infections that are treated with the formulation include both Gram negative and positive bacterium such as Pseudomonas and Staphylococcus (col. 3, lin. 43-47, col. 4, lin. 15-20). The formulation includes carriers such as gel-forming polymers and thickening agents (col. 8, lin. 41-col. 9, lin. 12). The reference is silent to the specific synergistic relationship between the chelator, buffer and antibiotic compounds; this relationship is well established as seen in the Farca study.

The Farca study investigated the relationship between EDTA-tromethamine complexes and various well known antibiotic compounds (abstract). The antibiotic compounds include ampicillin, cephalexin, and oxytetracycline (page 3). Formulations were formed using solutions comprising up to 250 mMol/L of EDTA and up to 5mMol/L of tromethamine (page 2). The minimum inhibitory concentrations were determined for each composition based on the specific bacterial strain, and the results were tabulated. It was found that a synergistic relationship was found for ampicillin and especially oxytetracycline against Gram Positive bacteria such as *Staphylococcus aures, hominis* and *Streptococcus faecium*. (page 2). It would have been obvious to apply the concentrations of the Farca study to the formulation of the '299 patent in order improve the synergistic bacterial fighting properties of the chelator/buffer/antibiotic combination.

The '443 patent discloses a topical wound healing composition comprising chelators such as EDTA (col. 11, lin. 18-20), antimicrobial agents such as tetracycline and amikacin (col. 10, lin. 20-22), along with buffers such as phosphate and tromethamine (TRIS) which maintain the pH of the formulation at 7.4 (col. 11, lin. 35-55). The drugs are present in a concentration from 0.1-60% (col. 11, lin. 28-31), while the buffer is present in a concentration of as much as 5%, which is sufficient to maintain the pH at 7.4 (col. 11, lin. 50-60). The formulation can be applied to wounds as a second skin that delivers active agents tot eh affected site (col. 5, lin. 1-5). It would have been obvious to include the buffer agents of the '446 patent into the formulation of the '299 patent since they both describe topical wound healing formulation comprising similar chelators, antimicrobial agents and buffering agents.

Regarding the specific concentration of the chelator compounds it is the position of the Examiner that such limitation in view of the prior art are obviated since the general conditions of the claims have been met by the prior art. It is the position of the Examiner that the concentration of chelators is merely an optimizable limitation as long as synergy is maintained. In each embodiment of the '299 patent synergy is maintained. Applicant is reminded that where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *See* In re Aller, 220 F.2d 454 105 USPQ 233, 235 (CCPA 1955).

Furthermore the claims differ from the reference by reciting various concentrations of the active ingredient(s). However, the preparation of various compositions having various amounts of the active is within the level of skill of one having ordinary skill in the art at the time of the invention. It has also been held that the mere selection of proportions and ranges is not

patentable absent a showing of criticality. *See* In re Russell, 439 F.2d 1228 169 USPQ 426 (CCPA 1971).

Regarding the claims limitation reciting the identification of a bacterial infection, determining the MIC and concentrations of the chelators and antibacterial agents, it is the position of the Examiner that such limitation are inherent to any treatment method and would be obvious to any artisan of ordinary skill. These steps are basic treatment steps and would be encompassed in the routine practice of the invention of the '299 and '433 patents. These steps are merely a recitation of inherent procedures practiced by every artisan of ordinary skill in the field of bacterial infections and do not impart patentability to the claims.

With these things in mind it would have been obvious to follow the suggestions and teachings of the prior art in order to provide an improved method of treating bacterial infections. The artisan of ordinary skill would have been motivated to combine the chelating concentration of the '979 patent into the treatment method of the '299 in order to maintain the synergistic properties of the components and improve the treatment of the infection. One of ordinary skill in the art upon combining these teachings, suggestions and disclosures would have expected a treatment method suitable for the disinfecting surface injuries.

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re*

Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1,2,5-11 and 56-62 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 14, 15, 18-21, 26-29, 43 and 44 of copending Application No. 10/739,841. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to methods of treating a wound with a composition comprising chelators and antibacterial agents. The claims recite the same chelators and antibacterial agents. Although the claims of the instant invention include further components, the claims of the '657 patent are open to further components that do not change the material properties of the invention. For these reasons the claims of the instant claims would act as obviating art over the '657 claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

3. Claims 1,2,5-11 and 56-62 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7, 9-19, 23, 24 and 28-43 of copending Application No. 10/812,668. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to a wound

chelating compositions comprising chelators, antibacterial and anti-inflammatory agents. The chelating agents are the same along with similar if not identical active agents. The claims also recite methods of application and kits comprising the formulation and methods of application. The claims of the copending application describe the formulation as a cleanser while the compositions of the instant claims are recited as a wound management composition. However the components of each composition are the same and perform the same function within the art. If issued the instant claims would act as obviating art over the '668 patents and vice versa.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant's arguments filed 12/8/09 have been fully considered but they are not persuasive. Applicant argues that:

The combination of the '299 patent, Farca study and the '443 patent does not obviate the instant claims since the combination does not disclose each limitation of the instant claims

Regarding this argument it remains the position of the Examiner that the combination continues to obviate the claims. Applicant argues that the '299 patent does not disclose a method of inhibiting proliferation of a bacterial population of a skin injury as described in the instant claims. However the '299 patent teaches a method of treating skin lesions including burns (col. 12, lin. 9-14) by contacting such lesion with a formulation comprising antimicrobial compounds such as erythromycin, minocycline and tetracycline in a concentration from 0.5-10% (col. 9, lin. 25-29), and chelating agents such as EDTA (claim 5) and a buffer where the buffer maintains the pH from 5.5-7.5 (col. 7, lin. 55-58). The reference is silent to a synergistic relationship between

the chelator and the antimicrobials, however the Farca study provides this disclosure. Applicant argues that the lytic enzyme present in the '299 patent somehow disqualifies the patent from disclosing elements of the instant claims. The instant claims are open and do not foreclose the inclusion of other functioning components that additionally solve the problem of inhibiting proliferation. The Farca study establishes the synergistic relationship between the chelating agent and antimicrobial compounds discussed in the '299 patent. Applicant argues that since lytic enzymes are not mentioned there would be no motivation to combine the references. However both references are within the same field of endeavor and discuss the same components being used to inhibit bacterial growth. The instant claims do not foreclose the inclusion of lytic enzymes since the claims are written with open claim language. As such there would have been motivation to modify the concentrations of the chelating agents, buffers and antibacterial agents in the '299 patent, as seen in the Farca study in order to optimize the effectiveness of these components against bacterial growth. This would have been obvious since both patents are within the same field of endeavor of reducing bacterial growth and solve the same problem of removing bacterial infections. Applicant argues that the '443 patent teaches away from the instant claims by the inclusion of counter ions that would counter act the action of the EDTA of other chelating agents. However the '443 patent is applied for its disclosure of the specific buffer agents in use with antibacterial formulation for use in treating topical lesions. Specifically buffers that maintain the pH between 5 and 9 and in the case of the '443 patent 7.4 (col. 12, lin. 30-35). Applicant argues that the chelating agent, specifically the EDTA would be complexed with the ionic polysaccharide and not be available for interaction with the antibacterial component. These arguments are merely speculative and are provided with no supporting

evidence. The '299 patent provides a formulation and method of use for treating skin lesion topically comprising a concentration of chelating agent, antimicrobial agents, buffers and additional excipients all within the limits of the instant claims. The 'Farca study connects the concentration of the chelating agent and antimicrobial compounds to show their synergistic properties when combined in proper amounts. The '443 study follows the suggestion of the '299 patent and provides the specific buffer composit0on useful for maintaining a safe pH. This combination of teachings and suggestions would have been obvious since each reference solves the same problem of reducing bacterial population by the application of chelators, buffers and antimicrobial compounds. For these reasons the claims remain obviated.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICAH-PAUL YOUNG whose telephone number is (571)272-0608. The examiner can normally be reached on Monday-Friday 8:00-5:30; every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
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/MICAH-PAUL YOUNG/
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